for commercial or charitable distribution, the following shall apply:

(1) When an ingredient is relied upon as a source of a nutrient(s) and when evidence indicates that such nutrient(s) in that ingredient is likely to be affected adversely by shipping or storage conditions, the manufacturer shall analyze that ingredient for each relied-upon nutrient that may be affected, using validated analytical methods.

(2) Ingredients, including nutrient premixes, that are either without a supplier's guarantee or certification, or not labeled as complying with prescribed standards, shall be sampled and analyzed for each relied-upon nutrient by the manufacturer, except that ingredients used as a major source of protein or fat need not be analyzed for each relied-upon nutrient if the manufacturer has records to show that each relied-upon nutrient is present at a reasonably constant level. Nutrient premixes prepared by the infant formula manufacturer shall be sampled and analyzed for each relied-upon nutrient. Nutrient premixes which are received from suppliers shall be sampled and analyzed for each relied-upon nutrient unless the supplier has sampled and analyzed each batch of premix for each relied-upon nutrient and has so certified in writing.

§ 106.25 In-process control.

(a) For each infant formula, a master manufacturing order shall be prepared and approved by a responsible official of the manufacturer. The manufacturer shall establish a quality control system that assures and verifies the addition of each ingredient specified in the manufacturing order.

(b) Unless each batch of finished product is analyzed as specified in § 106.30(b)(1), the manufacturer shall analyze each in-process batch for:

(1) Solids;

(2) Protein, fat, and carbohydrates (carbohydrates either by analysis or by mathematical difference);

(3) The indicator nutrient(s) in each nutrient premix;

(4) Each nutrient added independently of nutrient premixes during formulation of the product, except for linoleic acid, vitamin D, vitamin K, choline, inositol, and biotin; and

(5) Solids or an appropriate nutrient to confirm proper dilution when final dilution is made after performance of the analyses in paragraph (b) (1) through (4) of this section.

§ 106.30 Finished product evaluation.

(a) The manufacturer shall establish criteria for sampling and testing to ensure that each batch of infant formula meets the nutrient requirements of section 412(g) of the act or of regulations promulgated under section 412(a)(2) of the act before release of product for commercial or charitable distribution.

(b)(1) *Immediate analysis.* Before release of product for commercial or charitable distribution, the manufacturer shall analyze representative samples of each batch of finished product for:

(i) Specific nutrient(s) to assess process degradation; and

(ii) All nutrients not previously analyzed for by the manufacturers, unless each in-process batch is analyzed for nutrients as specified in § 106.25(b) and the ingredients are analyzed as specified in § 106.20(b). No analyses are needed for linoleic acid, vitamin D, vitamin K, choline, inositol, and biotin; and for nutrients that are added as a part of a nutrient premix analyzed by the manufacturer or having a supplier's guarantee or certification and for which an indicator nutrient(s) was analyzed by the manufacturer.

(2) *Periodic analysis.* The manufacturer shall sample at least one newly processed finished product batch every 3 months and shall analyze representative samples for all nutrients except those that the manufacturers measured in the immediate analysis of that product batch.

(3) *Stability analysis.* Using representative samples collected from finished product batches, the manufacturer shall conduct stability analysis for selected nutrients with sufficient frequency to substantiate the maintenance of nutrient content throughout the shelf life of the product.

(c) The manufacturer shall evaluate new formulations and the effect of changes in ingredients or processing conditions that could affect the level of

nutrients by means of a testing program designed to confirm uniformity of batches and to determine the effects of such changes. The following shall apply:

(1) A minor change is a minor reduction in nutrient levels, a minor increase in levels of nutrients that are subject to maximum limits established under section 412(g) of the act or in regulations established under section 412(a)(2) of the act, or any other change where experience or theory would not predict a possible significant adverse impact on nutrient levels or nutrient availability. After a minor change the manufacturer shall analyze representative samples for all nutrients so changed and those possibly affected by the change.

(2) A major change is any new formulation, or any change of ingredients or processes where experience or theory would predict a possible significant adverse impact on levels of nutrients or availability of nutrients. After a major change the manufacturer shall analyze representative samples for osmolality, all nutrients, and the biological quality of the protein. A protein biological quality analysis is not necessary for a formulation change that is not expected to have an adverse effect on the biological quality of the protein. Vitamin D shall be determined by the rat bioassay method as prescribed in ''Official Methods of Analysis of the Association of Official Analytical Chemists'' (AOAC), 13th Ed. (1980), sections 43.195–43.208, ''Vitamin D (30)—Official Final Action,'' which is incorporated by reference. Copies are available from the Association of Official Analytical Chemists International, 481 North Frederick Ave., suite 500, Gaithersburg, MD 20877–2504, or available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal__register/code__of__federal__regulations/ibr__locations.html.*Before release of the product for commercial or charitable distribution, the manufacturer shall have completed all appropriate analyses except that shipment of the product need not be delayed until results of the vitamin D bioassay and, if required, a protein biological quality bioassay are complete, provided such bioassays have been initiated, and if another analysis for the vitamin D has been run and the protein content has been determined by a suitable method. The biological quality of the protein shall be determined by an appropriate modification of the AOAC bioassay method of analysis. The manufacturer shall analyze additional samples from the same batch for vitamin D, by any suitable method, and for the biological quality of the protein. The manufacturer shall perform such analyses at least annually for a period not to exceed the expected shelf life of the product.

(d) A simple adjustment in the level of an ingredient to accommodate inconsistencies in processing is considered to be neither a minor nor a major change.

[47 FR 17025, Apr. 20, 1982, as amended at 54 FR 24891, June 12, 1989; 63 FR 14035, Mar. 24, 1998]

§ 106.90 Coding.

The manufacturer shall code all infant formulas in conformity with the coding requirements that are applicable to thermally processed low-acid foods packaged in hermetically sealed containers as prescribed in § 113.60(c).

Subpart C—Records and Reports

§ 106.100 Records.

(a) Every manufacturer of infant formula shall maintain the records specified in this regulation in order to permit the Food and Drug Administration to determine whether each manufacturer is in compliance with section 412 of the Federal Food, Drug, and Cosmetic Act (the act).

(b) The manufacturer shall maintain all records that pertain to food-packaging materials subject to § 174.5 of this chapter and that bear on whether such materials would cause an infant formula to be adulterated within the meaning of section 402(a)(2)(C) of the act.

(c) The manufacturer shall maintain all records that pertain to nutrient